

REMARKS

In response to the final Office Action of October 19, 2005, Applicants have amended claims 1 and 17 to recite "consisting essentially of" rather than "comprising", which when considered with the following remarks, is deemed to place the present application in condition for allowance. Entry of this amendment under 37 C.F.R. §1.116 and favorable consideration of all pending claims is respectfully requested.

In the final office action of October 19, 2005, the Examiner has maintained the rejection of claims 11-20 under 35 U.S.C. §103(a) as allegedly unpatentable over Hauer et al. (U.S. Patent No. 5,342,625). Applicants respectfully traverse the final rejection for the reasons set forth below.

On page 3 of the Office Action, the Examiner has referred to column 6, lines 47-50 of Hauer et al. in its disclosure of a composition that comprises cyclosporine, a hydrophilic phase, a lipophilic phase and a surfactant (column 6, lines 47-50). Applicants direct the Examiner to column 7, lines 19-68 and column 8, lines 1- 55 of Hauer et al., where examples of hydrophilic components are set forth and include:

(i) C₁₋₅ alkyl or tetra-hydrofurfuryl di- or partial-ethers of a low molecular weight mono- or poly-oxy-alkanediol (e.g., TRANSCUTOL, COLYCOFUROL) or

(ii) 1, 2-propyleneglycol.

Indeed, all of the working examples in Hauer et al. comprise either of these two types of hydrophilic components.

In contrast, presently amended claim 11 (and claims 12-16 depending therefrom) as well as presently amended claim 17 (and claims 18-20 depending therefrom), recite in relevant part, carrier compositions consisting essentially of (a) a sorbitan fatty acid ester co-surfactant; (b) a pharmaceutically acceptable oil which is essentially pure or

which is in the form of a mixture, comprising a triglyceride as essential lipophilic component and (c) a non-ionic surfactant. Thus, in contrast to Hauer et al., the presently claimed invention comprises cyclosporin in a carrier composition consisting essentially of a lipophilic phase, a surfactant, and a co-surfactant, *in the absence of a hydrophilic component*.

Applicants respectfully submit that claims 11-20 are patentable over Hauer et al. since Hauer et al. does not suggest a carrier composition consisting essentially of a sorbitan fatty acid ester co-surfactant, a triglyceride as an essential lipophilic component, and a non-ionic surfactant, in the absence of a hydrophilic component. There is simply no teaching provided by Hauer et al. that would suggest to, or motivate a skilled artisan to make the presently claimed compositions. Absent such a suggestion or motivation, the presently claimed invention is not obvious.

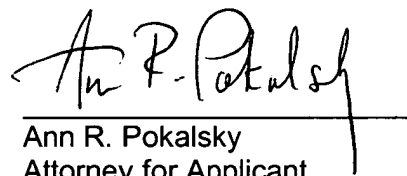
Moreover, Hauer et al. merely provides a "shotgun" disclosure listing multiple components to make up the surfactants, hydrophilic and lipophilic components. There is nothing in Hauer et al. to suggest to one skilled in the art to make the specific combinations of co-surfactant, lipophilic component and surfactant in the relative amounts and HLB values presently claimed.

In view of the foregoing, it is respectfully submitted that Hauer et al. fails to render obvious the subject matter of claims 11-20. Withdrawal of the rejection of claims 11-20 under 35 U.S.C. §103(a) is therefore warranted.

Applicants respectfully request that the Examiner enter this amendment and pass the application to allowance.

Respectfully submitted

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080


Ann R. Pokalsky
Attorney for Applicant
Reg. No. 34,697

Date: February 8, 2006